

## REMARKS

Applicants request favorable reconsideration of this application in view of the foregoing amendments and the following remarks. Of claims 1-25 that were pending in the application, claims 6, 7, 9-12, 15-18, 20, and 23-25 remain withdrawn from consideration and claims 1, 13, 14, 19, 21, and 22 were rejected. Applicants appreciate the allowance of claims 3-5 and the indication of allowable subject matter in claims 2 and 8, which depends from claim 2.

By way of this amendment, Applicants broadened the scope of claims 1-4, 13, 14, 19, 21, and 22 by replacing a recitation of “a therapeutic agent” with “particles,” *i.e.*, a term that includes all of the therapeutic agents listed on page 7 of the instant application. Support for this change is provided in original claims 19 and 22 and page 8, line 9. In addition, in response to the positive indication of allowable subject matter in claims 2 and 8, claim 2 has been amended to be in independent claim format. In addition to the aforementioned amendments, new claims 26-34 have been added. In light of these changes, claims 1-5, 8, 13, 14, 19, 21, 22, and 26-34 are respectfully submitted for further consideration.

### **1. Rejection of Claims 1, 13, 14, 19, 21, and 22**

The Examiner rejected claims 1, 13, 14, 19, 21, and 22 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,010,478 (“Bellhouse-I”). Preliminarily, this rejection could be overcome, as suggested by the Examiner, by showing that the invention described in Bellhouse-I was not “by another,” as required by § 102(e). However, Applicants note that the sealed capsule 8 to which the Examiner cited was previously disclosed as a capsule 28 in WO94/24263 (“Bellhouse-II”) (*see* Figs. 1 and 8) and in its related U.S. Patent No. 5,630,796 (“Bellhouse-III”) (*see* Fig. 1). Bellhouse-II and Bellhouse-III were submitted in the Information Disclosure Statement (“IDS”) filed on July 26, 2003, which the Examiner acknowledged in the Office Action mailed April 22, 2004. Accordingly, as Bellhouse-II was published on October 27, 1994 and as Bellhouse-III issued on May 20, 1997, both references qualify as prior art under 35 U.S.C. § 102(b). As a result, the rejection will be addressed and traversed with respect to Bellhouse-II, as it is the oldest of the three references.

Independent claims 1, 14, and 22 all recite a “capsule” or “intermediate portion” that includes first and second members. With respect to the first and second members, one of the members “is movable *relative* to the other member” such that “upon said *relative movement* a passage is formed through said capsule and said pocket is opened to expose the dose for entrainment in fluid flowing through said passage.” As hereafter explained in detail,

Bellhouse-II (along with Bellhouse-I and Bellhouse-III) fails to teach or suggest such a capsule/intermediate portion.

The capsule 28 disclosed in Bellhouse-II is best illustrated in Figure 8, which shows a compartment 32 formed between two diaphragms 33, 34. *See* Bellhouse-II at p. 17, lines 23-28. The lower diaphragm 34 may be dimpled downward. In other words, as shown in Figure 8, the shape of the diaphragm 34 shown in solid lines may be replaced by an alternate shape shown in dashed lines, *i.e.*, the dashed line that indicates the dimpling of the diaphragm 34 is not an indication that the diaphragm 34 moves (relative to the other diaphragm 33) between the solid line and the dashed line. *See id.* at lines 33-36.

In use, the capsule 28 reacts as follows: when an internal pressure of a chamber 25, which is behind the capsule 28, rises above a threshold, both diaphragms 33, 34 burst, thereby creating a passage for the particles. *See id.* at p. 19, lines 15-19. As a result of this functionality, Bellhouse-II fails to teach or suggest at least two limitations recited in claims 1, 14, and 22. First, as *both* diaphragms 33, 34 burst, neither diaphragm moves “relative to the other.” Second, it is the movement of *both* diaphragms 33, 34 that creates a passage for the particles.

In contrast, claims 1, 14, and 22 recite that only one member moves (relative to the other member) and it is this movement that creates the passage. An example of the movement recited in these claims is clearly shown in Figs. 16/17 (*i.e.*, the figs. corresponding to the elected embodiment), which show the plug 79 moving with respect to the capsule housing 78; in the intermediate position (not shown) of the plug 79 a passage is created similar to that shown for the non-elected embodiments shown in Figs. 2/3 and 8/9.

For at least both of the aforementioned reasons, Bellhouse-II fails to teach or suggest each of the limitations of independent claims 1, 14, and 22. Moreover, as Bellhouse-I and Bellhouse-III disclose the same capsule as Bellhouse-II, neither Bellhouse-I nor Bellhouse-III cures the deficiencies of Bellhouse-II. As a result, none of Bellhouse-I, Bellhouse-II, and Bellhouse-III can be used, under 35 U.S.C. § 102(b), to reject claims 1, 14, and 22, or any claim dependent thereon. Moreover, as claim 13 depends from claim 1 and as claims 19 and 21 depend from claim 14, each of these dependent claims is also allowable over Bellhouse-I, Bellhouse-II, and Bellhouse-III. Accordingly, Applicants respectfully request a withdrawal of the rejection of claims 1, 13, 14, 19, 21 and 22.

**2. New Claims 26-34**

New independent claim 26 recites the same structural subject matter as claim 1; the only difference between claims 1 and 26 is that claim 26 recites a “a dose of a therapeutic agent” whereas claim 1 recites “a dose of particles.” In light of the structural similarities between claims 1 and 26, claim 26 (and its depend claims 27-28) is allowable over Bellhouse-I, Bellhouse-II, and Bellhouse-III for at least the same reasons previously set forth with respect to claim 1.

New dependent claims 29-34 respectively depend from claims 1-4, 14, and 22. As a result, these dependent claims are also allowable over Bellhouse-I, Bellhouse-II, and Bellhouse-III for at least the same reasons previously set forth with respect to claims 1, 14, and 22.

**3. Previously Withdrawn Claims**

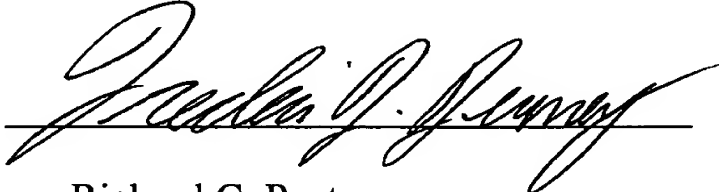
As withdrawn claims 10-12 depend from allowable claim 1, as withdrawn claim 9 depends from allowable claim 2, as withdrawn claims 6 and 7 depend from allowable claim 4, and as claims 15-18, 20, and 23-25 depend from allowable claim 14, each of these dependent/withdrawn claims is also allowable. Accordingly, when issuing a Notice of Allowance, the Examiner is requested, under 37 C.F.R. § 1.141 and M.P.E.P. § 809.04, to reenter and allow claims 6, 7, 9-12, 15-18, 20, and 23-25.

**CONCLUSION**

For the aforementioned reasons, claims 1-34 are now in condition for allowance. A Notice of Allowance at an early date is respectfully requested. The Examiner is invited to contact the undersigned if such communication would expedite the prosecution of the application.

Respectfully submitted,

Date 11/7/05

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY ADDITIONAL FEES WHICH MAY BE REQUIRED REGARDING THIS APPLICATION UNDER 37 C.F.R. §§ 1.16-1.17, OR CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 19-0741. SHOULD NO PROPER PAYMENT BE ENCLOSED HEREWITH, AS BY A CHECK BEING IN THE WRONG AMOUNT, UNSIGNED, POST-DATED, OTHERWISE IMPROPER OR INFORMAL OR EVEN ENTIRELY MISSING, THE COMMISSIONER IS AUTHORIZED TO CHARGE THE UNPAID AMOUNT TO DEPOSIT ACCOUNT NO. 19-0741. IF ANY EXTENSIONS OF TIME ARE NEEDED FOR TIMELY ACCEPTANCE OF PAPERS SUBMITTED HEREWITH, APPLICANT HEREBY PETITIONS FOR SUCH EXTENSION UNDER 37 C.F.R. § 1.136 AND AUTHORIZES PAYMENT OF ANY SUCH EXTENSIONS FEES TO DEPOSIT ACCOUNT NO. 19-0741.